Opening Statement of Chairman Tom Davis
Government Reform Committee Hearing
Potential Reduced-Risk Products: An examination of the Regulatory Challenges and Public Health Implications

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Tobacco smoke is the cause of a great many illnesses, among them cancer, cardiovascular disease and stroke. Indeed, over 400,000 Americans die every year from tobacco-related illness – the leading preventable cause of death. Imagine if this same number died from a communicable disease such as SARS or smallpox. The mere threat of such illnesses has been sufficient to garner far greater public attention and response.

We are left with the question of how best to respond to this situation. While smoking rates steadily declined from the 1960's to the end of the 1980's, we have reached something of a plateau since the early 1990's. According to the most recent figures, approximately one quarter of the adult population smokes – 47 million people. Of this number, 70 percent express a desire to quit. While 34 percent of this number will make an attempt to do so annually, less than 3 percent will succeed. These numbers beg the question of whether current approaches to controlling tobacco-related morbidity and mortality are sufficient.

In recent years, we have seen pharmaceutical products such as the patch and nicotine gum emerge as cessation aids. We are also seeing the emergence of the "harm-reduction" tobacco market -- that is, products that aim to decrease harm to health from tobacco use without completely eliminating it. This latter form of product is largely unregulated, and there are questions whether these products, which give the impression of being a safer alternative to conventional cigarettes, are in the public interest.

In 1999, the Food and Drug Administration (FDA), requested that the Institute of Medicine (IOM) conduct a thorough study into tobacco harm reduction products. In 2001, IOM published the seminal work on the subject, entitled *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction.* It is this study and its recommendations that serve as the basis for our hearing today.

Clearing the Smoke makes a number of recommendations and sets out a number of principles for the ideal regulatory scheme to oversee harm reduction products (referred to as Potential Reduced Risk Products, or PREPs, in the study) and tobacco in general. However, as I read the study, the take-away messages are these:

1. It is feasible, but not easy, to produce tobacco products that could expose the consumer to lower levels of toxins than conventional cigarettes.

2. It is possible that reduced exposure to these toxins could reduce the risk of tobacco-related disease and death.
3. Great care must be taken to ensure these products do not result in increased harm to individuals and to the public's health in general.

Said another way, harm reduction presents both promise and uncertainty. There is still much that we do not know about tobacco-related illness, nor do we fully understand why people smoke cigarettes in the first place. Finding the answers to these questions is a critical component in harm-reduction efforts.

Tobacco harm reduction is not without its critics. As I mentioned earlier, a core concern with these products is that while they may be able to remove a degree of the risk from the individual user, the notion of a "safer" product could prove damaging to the population as a whole. Smokers who might otherwise quit tobacco use altogether could instead opt to use the "safer" products. In addition, those who had already quit smoking could be enticed to start anew. Finally, children, a group already convinced of their own invincibility, could be drawn to a life of tobacco-dependency by the lure of "safe" tobacco.

History bears out these concerns. Earlier attempts at harm reduction, most notably the advent of the filtered cigarette, later followed by low-yield cigarettes, were heralded by the public health community. However, time has shown these were false hopes. While the vast majority of cigarettes today are filtered, there has been no discernable decrease in morbidity or mortality. Similarly, while low-tar cigarettes may have produced lower toxins as measured by an automated device, human consumers changed their smoking behavior (by inhaling more deeply, for example) to leach out the same nicotine and tar levels found in other cigarettes. In the wake of these products, smoking rates increased and the public health suffered. To this day, most smokers use light or low-tar products, despite the information available that they offer little, if any, improvement over other products. The perception of safety is hard to break.

These concerns are well taken and must be given due consideration as we move forward. However, given the fact that a significant number of people will continue to use tobacco for the foreseeable future, I am not of the opinion that these concerns merit abandoning tobacco harm reduction in favor of an abstinence-only approach. That said, development of this marketplace must take place in the proper regulatory environment. A scientific agency, in my opinion the Food and Drug Administration, should oversee all tobacco products, but especially products intended to be sold for harm-reduction purposes.

Currently, our regulatory structure has been turned on its ear. Based on the IOM study, as well as works from a great many experts, including some of those on our panel today, it seems obvious that pharmaceutical nicotine therapies present the least amount of risk of any potential reduced-exposure product. Yet they are subjected to the most stringent regulatory examination. Perhaps as a result, they are quite expensive, and there are few options available to the consumer. Ironically, potential reduced-exposure products made from tobacco, which are regarded as the most-risky form of these products, are subjected

to little, if any regulation at present. I believe we should not only look for ways to increase regulation of tobacco products, but also at ways in which FDA can facilitate a vibrant medicinal nicotine market.

Finally, I believe it is important to achieve balance in our efforts at tobacco harm reduction. As the IOM states, manufacturers must be given the incentive to develop and market products that reduce exposure to tobacco toxicants and that have a reasonable prospect of reducing the risk of tobacco related disease. This incentive comes in the form of being able to communicate the message that a given product does just that. These claims must be based on good science, but if the science is there, undue skepticism of regulators should not discourage development.

The facts are these: Many experts believe harm-reduction could play an important role in decreasing tobacco-related disease and death. If this is to work, and if the American people are to benefit, two parties with little regard for each other are going to have to learn to coexist.

Future regulators and public health officials need the ingenuity and resources the industry can bring to bear to create palatable, acceptable, and less-risky products that current smokers will use. The industry needs independent government regulators to validate its science and confirm the value of the products they wish to market to the public. Anything less will surely return us to the days of snake oil.

We must be prepared to work past old notions regarding tobacco products. In this vein, we will consider today the role smokeless tobacco plays in this debate. Some believe there is scientific evidence that smokeless does, in fact, represent a significant decrease in risk compared to conventional cigarettes. If this is so, what do we do with this information?

In closing, there are a great many questions to be answered regarding potential reduced-exposure products. We have constructed two panels that I believe will help us understand many of the relevant issues, and I very much look forward to today's hearing.

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